510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(21 CFR 807.92)

for the *LumiLoc™ Safety Introducer Needle*

SUBMITTER:

Specialized Health Products® International, Inc.
585 West 500 South, Suite 200
Bountiful, Utah 84010

JUN 14 2007

ESTABLISHMENT REGISTRATION NUMBER:

1723684

CONTACT:

Mark Nelson
Director, Quality and Regulatory Affairs
Telephone: 801-298-3360
Fax: 801-298-1759
Email: **marknelson@shpi.com**

DATE PREPARED:

2/14/2007

NAME OF MEDICAL DEVICE:

Classification Name: Tube, Gastrointestinal (and Accessories)
Common/Usual Name: Safety Percutaneous Endoscopic Gastrostomy Introducer
Proprietary Name: ***LumiLoc™ Safety Introducer Needle***

DEVICE CLASSIFICATION:

Classification Panel: Gastrointestinal/Urology
Class: II
Product Code: 78 KNT
Regulation Number: 21 CFR 876.5980

STATEMENT OF SUBSTANTIAL EQUIVALENCE (Predicate Device References):

1. *SecureLoc™ Safety Introducer (K050023), Specialized* Health Products® International, Inc., 585 W. 500 S., Bountiful, UT 84010.
2. *Modified TFX Medical Safety Needle with Introducer (K043258),* Teleflex Medical, Inc., 50 Plantation Drive, Tall Pines Park, Jaffrey, NH 03452.

DEVICE DESCRIPTION:

The LumiLoc™ Safety Introducer Needle consist of a stainless steel trocar/needle with a colored translucent hub and a colored translucent safety guard, a sheath attached to a translucent hub having a standard female Luer lock hub connector. The trocar/needle hub has a bevel-up orientation indicator. The sheath hub utilizes a phosphorescent material. The LumiLoc™ Safety Introducer Needle's sheath hub has an integral Seldinger shield. The stainless steel trocars/needles have a specialty coating to enhance percutaneous entry.

The LumiLoc™ Safety Introducer Needle incorporates an intuitive easy to use safety guard which is an integral part of the device. The LumiLoc™ Safety Introducer Needle's engineered integral safety guard is passively activated by the clinician upon removal of the trocar/needle from the introducer sheath and helps to reduce the risk of accidental trocar/needlestick injuries by locking a safety guard over the trocar/needle tip. A visual, tactile, or audible confirmation of the locking component over the trocar/needle confirms lockout of the safety guard over the trocar/needle.

LumiLoc™ Safety Introducer Needles will be marketed to the clinical end-user as sterile single use devices. Additionally, the device will be placed in Percutaneous Endoscopic Gastrostomy (PEG) procedural trays. In the case of being used in procedural kits, the product will be shipped bulk non-sterile to the procedural tray or kit manufacturer. The LumiLoc™ Safety Introducer Needles will be incorporated into a procedural tray or kit, packaged and sterilized.

INTENDED USE:
The device is intended to be used for guidewire introduction during percutaneous gastrointestinal procedures.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:
It is Specialized Health Products® International, Inc.'s conclusion that the **LumiLoc™ Safety Introducer Needles** are substantially equivalent to the following devices: *SecureLoc™ Safety Introducer (K050023),* Specialized Health Products® International, Inc., 585 W. 500 S., Bountiful, UT 84010 and the *Modified TFX Medical Safety Needle with Introducer (K043258),* Teleflex Medical, Inc., 50 Plantation Drive, Tall Pines Park, Jaffrey, NH 03452.

A summary of the key technological comparisons follows:

- The LumiLoc™ Safety Introducer Needles are similar in clinical use, function, materials and use as compared to both predicate percutaneous introduction devices.
- The LumiLoc™ Safety Introducer Needles and the *SecureLoc™ Safety Introducer* predicate device use the same safety technology – made by the same company (Specialized Health Products® International, Inc.) – to lock a safety guard over the trocar/needle tip after the trocar/needle is removed from the patient. The TFX predicate also utilizes a safety mechanism to protect the trocar/needle tip.
- The LumiLoc™ Safety Introducer Needle's safety guard lock-out can be confirmed by visual, tactile or audible means, as do both predicate devices cited in this submission.

SUMMARY OF PERFORMANCE TESTING:
Comparative testing has been performed on the LumiLoc™ Safety Introducer Needles and the predicate devices. Test results indicate that the LumiLoc™ Safety Introducer Needles perform in a substantially equivalent manner to the predicate devices.

SUMMARY OF SIMULATED USE STUDY:

A total of 500 LumiLoc™ Safety Introducer Needles were successfully inserted by clinicians into simulated tissue and activated. No sharps injuries or failures of the integral safety guard occurred.

CONCLUSION:

The material testing and simulated use test data demonstrate that the LumiLoc™ Safety Introducer Needle is safe and effective for its intended use, comply with medical device standards, and is substantially equivalent to:

- *SecureLoc™ Safety Introducer (K050023),* Specialized Health Products® International, Inc., 585 W. 500 S., Bountiful, UT 84010.
- *Modified TFX Medical Safety Needle with Introducer (K043258),* Teleflex Medical, Inc., 50 Plantation Drive, Tall Pines Park, Jaffrey, NH 03452.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 14 2007

Mr. Mark Nelson
Director, RA/QA
Specialized Health Products International, Inc.
586 West 500 South, #200
SALT LAKE UT 84010

Re: K070449
Trade/Device Name: Lumiloc Safety Introducer Needle
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 29, 2007
Received: May 30, 2007

Dear Mr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070449

Device Name: ***LumiLoc™ Safety Introducer Needle***
Indications for Use:

The LumiLoc™ Safety Introducer Needle is intended to be used for percutaneous procedures utilizing a sheathed introducer trocar/needle for guidewire introduction during percutaneous gastrointestinal procedures.

The LumiLoc™ Safety Introducer Needle's engineered integral safety guard is passively activated by the clinician upon removal of the trocar/needle from the introducer sheath.

The LumiLoc™ Safety Introducer Needle helps to reduce the risk of accidental trocar/needlestick injuries by locking a safety guard over the trocar/needle tip.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070449